



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

MAERTENS et al

Atty. Ref.: 2551-97

Serial No. 09/686,964

Group: 1648

Filed: October 12, 2000

Examiner: Hill

For: IMPROVED IMMUNODIAGNOSTIC ASSAYS USING REDUCING AGENTS

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September 21, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REQUEST

The Examiner is requested to return an initialed copy of the PTO-1449 Form filed June 14, 2004, pursuant to MPEP § 609 as copies of the references were filed and received by the Patent Office on June 14, 2004. A copy of the undersigned's postcard receipt indicating receipt of the two (2) cited documents in the Patent Office on June 14, 2004, is attached.

Moreover, attached is a copy of the Patent Office PAIR Image File Wrapper Index which confirms receipt of a "foreign reference" on June 14, 2004. The indicated "foreign reference" is indicated as being 97 pages. The undersigned has reviewed this "foreign reference" and found that the Patent Office has scanned both documents filed June 14, 2004, as a single document. The first page of each of the cited documents which were previously supplied to the Patent Office and are available to the Examiner under "foreign reference" received in the Patent Office on June 14, 2004, is attached.

Specifically, the first page of WO 96/06355 and the first page of WO 91/15575, each listed on the PTO-1449 Form filed June 14, 2004, is attached for the Examiner's reference. The Examiner is requested to return an initialed copy of the PTO-1449 Form filed June 14, 2004, pursuant to MPEP § 609, as nothing further is believed to be required.

The Examiner is also requested to acknowledge acceptance of the formal drawings or provide a specific objection or rejection of the same.

The present paper is not being filed in response to the Office Action of September 9, 2004.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By:

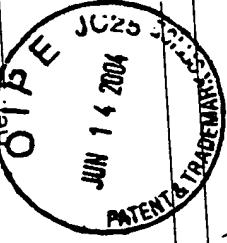


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Atty: BJS
Date: June 14, 2004
Client: 2551-97

Serial No.: 01/686964
Applicant: Martens
Title: Impaired immunodiagnostics



Amendment
Pages Specification
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 Declaration (_____ Pages)
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ENGLISH TRANSLATION OF REFERENCE 1

REAGENT FOR ASSAY OF ANTIBODY AGAINST REDUCED ANTIGEN AND METHOD FOR DETERMINATION USING THEM**Field of invention**

The present invention relates to assay for identifying the presence of an antibody having immunological reactivity to a hepatitis C virus (HCV) antigen in sample, in particular to converting cysteine residue existing in said antigen into a reduced form or reduced derivative or retaining it to detect the antibody having a specific reactivity to said reduced antigen or a derivative thereof. NS3 domain of HCV genome, in particular, 33C antigen in which a cysteine residue is converted into a reduced form or a reduced derivative or retained being its reduced form is useful as a reagent for detection of antibody in a body fluid of individual infected by a hepatitis C virus (HCV). In particular, the present invention relates to a reagent for determining to high sensitively and correctly determine an antibody against a hepatitis C virus (HCV).

Background of the invention

It has been found that acute viral hepatitis is caused by a virus such as hepatitis A (HAV) virus and hepatitis B virus (HBV). However acute viral hepatitis which an antibody against those HAV or HBV, cytomegalovirus, Epstein-Barr virus are undetectable has been clinically found, and it was proposed to call it non-A non-B hepatitis (NANBH). It has been successful to develop excellent tests for HBV, therefore nowadays the great majority of post-transfusion hepatitis have been non-A non-B hepatitis, from that point of view it has been desired to develop an effective test of non-A non-B hepatitis.

In such a situation, non-A non-B hepatitis factor cloned from chronic non-A non-B hepatitis infected chimpanzee by gene recombinant technology was called hepatitis C virus (HCV) (EP-A-0318216), EP-A-0388232).

As method for diagnosing the infection with hepatitis C virus (HCV), HCV antibody measurement system using C100-3 antigen was developed by Chiron Corporation, USA in 1988. It has been reported that said antigen called C100-3 contains 154 amino acid residues derived from human superoxide dismutase (SOD), 5 amino acid residues derived by expression of a synthesis DNA adapter containing EcoRI restriction enzyme site, 363 amino acid residues derived by expression of cDNA fragment from cloned HCV genome, and 5 amino acid residues being in 5 carboxy-terminal derived from MS2-cloning vector DNA in its amino-terminal.

In 1991, HCV antibody measurement system was developed, having the superior sensitivity and detection rate using core domain and C33 antigen coded by NS3 domain unduplicating C100-3 antigen being structural domain on HCV genome. Furthermore, the use of an antigen coded in NS4 domain has been tried. In order to determine those HCV antibody, methods such as aggregation method using erythrocyte or latex particle as an antigen supporting carrier, and immunometric method using beads, tube or plate as an antigen immobilizing carrier have been used.

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : C12N 9/50, 15/51, 15/57 C12N 15/62, C12Q 1/37		A1	(11) International Publication Number: WO 91/15575 (43) International Publication Date: 17 October 1991 (17.10.91)
(21) International Application Number: PCT/US91/02210 (22) International Filing Date: 4 April 1991 (04.04.91)		(81) Designated States: AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GA (OAPI patent), GB (European patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL (European patent), NO, PL, RO, SD, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent).	
(30) Priority data: 505,433 4 April 1990 (04.04.90) US		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
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(74) Agents: CIOTTI, Thomas, E. et al.; Irell & Manella, 545 Middlefield Road, Suite 200, Menlo Park, CA 94025-3471 (US).			

(54) Title: **HEPATITIS C VIRUS PROTEASE**

(57) Abstract

The protease necessary for polyprotein processing in Hepatitis C virus is identified, cloned, and expressed. Proteases, truncated protease, and altered proteases are disclosed which are useful for cleavage of specific polypeptides, and for assay and design of antiviral agents specific for HCV.